Appl. No.	:	10/606,982	Confirmation No. 6440
Applicants	:	Lewis, Michael	
Filed	:	06/26/2003	
TC/A.U.:		3764	
Examiner	:	Demille, Danton	
Docket No.	:	244.002	
Customer No. :		9809	

Response of 24 June 2005 to Restriction Requirement of 8 June 2005

REMARKS/ELECTION

In response to the Office restriction notice of 8 June 2005, Applicant, through its counsel of record, has amended the preamble of claim 1 to rejoin Groups I and III. Claims 12-22, identified by the Examiner as Group II have been withdrawn

I. ELECTION

Applicant therefore elects to proceed on claims 1-11 and 23-31.

II. BASIS OF JOINDER FOR CLAIMS 1-11 AND 23-31

A. APPARATUS INHERENTLY MUST BE USED WITH NEED FOR SENSING PHYSIOLOGICAL DATA, AS FOUND IN CLAIM 23.

Applicant believes Claim 1 and those dependent therefrom and Claim 23 and those dependent therefore should be joined. The Examiner assessed Claim 23 as a separate species because "[i]n this case the apparatus can be used without the need for the sensing physiological data." However it is not possible to use the "cuff for use in counterpulsation treatment of a patient wherein pressure is applied to said patient's blood vessels to stimulate blood flow" without sensing physiological data. As defined in the specification:

> Counterpulsation has traditionally involved the application of sequential pressures on the lower legs, upper legs and buttocks through pneumatic cuffs placed on those regions. Application of pressure to the extremities has been timed to correlate with a patient's physiological rhythms, such as diastolic and systolic phases of the heart. This application of force by the cuff pushes blood upward toward the heart, whereby blood pressure is increased during the diastolic phase of the heart. This enhanced pressure is recognized as medically beneficial for treatment of medical conditions relating to blood circulation.

Specification, page 6, Lines 14-21.

This requirement for correlation between application of pressure from the cuff and physiological conditions is inherent in the treatment and is well known in the art. See the attached website from the Mayo Clinic, attached as Exhibit 1, which provides

> These cuffs are quickly inflated with compressed air during the resting phase of the heartbeat. When the heart contracts, the cuffs are deflated. This inflation/deflation of the cuffs forces blood to the heart, increases the heart's output and may help the heart develop better circulation.

Exhibit 1, Mayo Clinic External Counterpulsation Treatment for Refractory Angina.

B. EXISTING STATEMENT OF APPLICABLE MEDICAL TREATMENT IS LIMITATION AS NECESSARY TO GIVE LIFE AND MEANING TO REMAINDER OF CLAIM

The existing statement of the applicable medical treatment is a limitation which therefore joins Claim 1 to Claim 23. It has long been the case that if the preamble is "necessary to give life, meaning, and vitality" to the claim, then it should be construed as a claim limitation. *See, e.g., Kropa v. Robie*, 187 F.2d 150, 152 (CCPA 1951). It is also established that if the preamble merely states the purpose or intended use of the invention, then the preamble cannot be said to constitute or explain a claim limitation and is of no significance to claim construction. See, e.g., *Pitney Bowes Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999). In this particular application, "for use in counterpulsation treatment of a patient wherein pressure is applied to said patient's blood vessels to stimulate blood flow," should be regarded as providing a limitation as it limits the use of the cuff to a specific medical treatment and thus gives life and meaning to the cuff. In *Griffin v. Bertina*, 285 F.3d 1029 (Fed. Cir. 2002), the Court of Appeals

for the Federal Circuit (CAFC) addressed a similar situation regarding a claim directed to a medical diagnosis. The count was:

> A method for diagnosing an increased risk for thrombosis or a genetic defect causing thrombosis comprising the steps of: (A) obtaining, from a test subject, test nucleic acid comprising codon 506 within EXON 10 of the human Factor V gene; and (B) assaying for the presence of a point mutation in the nucleotides of codon 506 within EXON 10 of the human factor V gene,...wherein the presence of said point mutation in said test nucleic acid indicates an increased risk for thrombosis or a genetic defect causing thrombosis." 285 F.3d at 1031.

At issue was whether the language "for diagnosing an increased risk of thrombosis or a generic defect causing thrombosis" constituted a limitation. The CAFC noted that diagnosis was the essence of the claimed invention and "its appearance in the count gives 'life and meaning' to the manipulative steps." *Id.* at 1033. The CAFC held that the manipulative steps of obtaining nucleic acid and assaying for a point mutation "have little meaning or utility unless they are placed within the context of the diagnosis of an increased risk of developing thrombosis, recited in the preamble and 'wherein' clauses." *Id.* Likewise in the present invention, the structure of the cuff in Claim 1 has little meaning or utility unless it is placed within the context of a specific type of medical treatment, namely external counterpulsation treatment.

C. AMENDMENT TO PREABLE IS LIMITATION AS NECESSARY TO GIVE LIFE AND MEANING TO REMAINDER OF CLAIM

Applicant's amendment to Claim 1 to explicitly require the physiological data correlation results in rejoinder of Claim 1 and Claim 23. The amendment to the preamble of Claim 1, explicitly limits the scope of use of the "cuff for use in counterpulsation treatment of a patient wherein pressure is applied to said patient's blood vessels to stimulate blood flow" to use where

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such pressure is "correlated with a patient's physiological rhythms based on data received from at least one physiological measuring device" results in a limitation. The limitation in question is "necessary to give life, meaning, and vitality" to the claim as it is necessary for counterpulsation treatment that the application of pressure be "correlated with a patient's physiological rhythms based on data received from at least one physiological measuring device." Therefore the apparatus requires use of physiological data which constitutes a limitation which traverses the Examiner's basis for a separate species, namely "[i]n this case the apparatus can be used without the need for the sensing physiological data."

III GRAMMATICAL AMENDMENTS

Applicant has amended Claims 1 and 23 to address inconsistencies.

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